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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,208	05/10/2001	Jian Chen	P1381R1D1	8512

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GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/854,208	CHEN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *66-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *66-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Applicant's amendment in paper No. 17, filed on 10 March 2003 is acknowledged and entered.

Currently, claims 66-82 are pending and under consideration.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 66-82 remain rejected under 35 U.S.C. 102(e) as being anticipated by Ebner et al., US 2003/0003545, for the reasons set forth in the last Office Action, paper No. 16, mailed on 24 February 2003, at page 3.

Applicants argument, filed on 10 March 2003 (paper No. 17) has been fully considered, but is not deemed persuasive for reasons below.

At page 2 of the response, the applicant argues that the Ebner reference has a filing date of May 27, 1999, and applicants pending application claims priority to US application 09/311,832, filed on May 14, 1999, which predates the filing date of May 27, 1999 of the Ebner reference, and therefore, it neither anticipates nor makes obvious the present invention. This argument is not persuasive because even though the Ebner reference has a filing date of May 27, 1999, it claim priority to US provisional applications, 60/131,965, 60/099,805 and 60/087,340, all of which have an earlier filing date than that of 09/311,832. Therefore, the cited reference remains anticipating the present claims.

Claims 66-68 and 71-80 are rejected under 35 U.S.C. 102(e) as being anticipated by Gorman et al., US 6,562,578 B1.

Gorman discloses a human polypeptide of IL-17 family, which amino acid sequence of SEQ ID NO:23, and is 100% identical to SEQ ID NO:3 of the present invention (see appended computer printout of sequence search result). Further, a signal sequence of 17 amino acids is indicated in Gorman's SEQ ID NO:23 (-17 to -1), which suggests that the mature polypeptide lacks the signal peptide. Therefore, the cited sequence anticipates claims 71-80. With respect to claims 66-68, although Gorman does not explicitly teach a composition of the polypeptide and a pharmaceutically acceptable carrier, however, it is well known in the art that a purified protein is usually used in combination with other agent(s), such as dissolving solutions, and can not be (rather than) used as its crystal form alone. Dissolving solutions, such as water, buffers, or media, meet the limitation of being "a pharmaceutically acceptable carrier". Thus, in view of Gorman's disclosure, one of ordinary skill in the art would consider that Gorman is in possession of such a composition. Therefore, the reference anticipates claims 66-68.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 69 and 70 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman et al., US 6,562,578 B1.

The teachings of Gorman are reviewed above. Gorman does not explicitly teach an article containing a composition of the polypeptide.

However, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to make an article containing said composition and instructions for the purpose of research and/or clinical applications, such as immunoassays or binding assays, because such an article would facilitate the applications, and commercial distribution. Further, packing a composition in an article is old and well known in the art.

Claims 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman et al., US 6,562,578 B1, as applied to claims 71-80 above, and further in view of Capon et al., US5,116,964.

The teachings of Gorman are reviewed above. Gorman does not teach a fusion protein of said polypeptide.

Capon discloses a novel polypeptide comprising an immunoglobulin Fc region, and a target protein sequence (column 5, lines 13-20). The cited reference indicates that fusion of a target protein to a stable plasma protein such as an immunoglobulin constant domain extends the in vivo plasma half-life, and facilitate purification of the protein (column 4, lines 38-43, and column 5, lines 13-20).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to use Gorman's polypeptide to make a fusion polypeptide comprising said polypeptide and an Ig constant region sequence as taught by Capon. One of ordinary skill in the art would have been motivated to make such a fusion polypeptide in order to obtain the advantage as taught by Capon, such as facilitating protein purification, and reasonably would have expected success in view of Capon's disclosure, in which various fusion proteins had already been made successfully at the time the invention was made.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
5/19/03

Lorraine Spector
LORRAINE SPECTOR
PRIMARY EXAMINER